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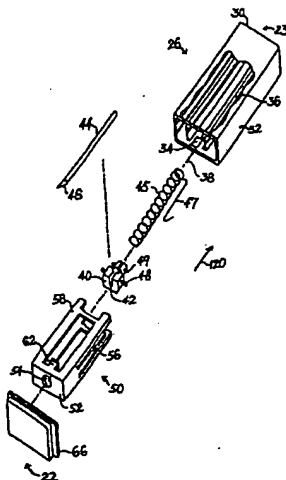
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(54) Title: LANCET ASSEMBLY



(57) Abstract: A lancet assembly having a lancet holder and a trigger enclosing a lancet structure. The trigger is partially inserted into a lancet holder from the distal end. The holder is provided with a rigid internal spring holder to receive the spring-loaded lancet structure. The lancet structure is provided with a body coupled to a spring which extends from the proximal end of the body. The spring has a linear axis of compression which coincide with the longitudinal axis of the lancet assembly. A lancet is attached to the body with the sharp tip pointing towards the distal end. The trigger interacts with the lancet holder via a triggering element to maintain the spring in a compressed state such that the lancet structure is in a stable standby position which is not easily triggered by accidental bumps on the assembly.

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1                                    **LANCET ASSEMBLY**

2

3            **FIELD OF THE INVENTION**

4            The present invention is related to finger-pricking devices. In  
5            particular, the present invention is related to lancets for medical use.

6

7            **BACKGROUND OF THE INVENTION**

8            Lancets or finger-pricking devices is widely used in the medical field  
9            for applications such as skin incisions and blood drawing. In some  
10           lancet assemblies, the blade or needle is kept in a standby position  
11           until it is triggered by the user, who is typically a medical personnel in  
12           charge of drawing the blood from a patient. In other lancet assemblies,  
13           the user has to manually set the assembly to an armed position before  
14           firing can be triggered. Upon triggering, the blade fires onto the skin of  
15           the patient, for example on the finger, and makes an incision.

16           Such lancet assemblies must be sterilized before use, and the  
17           lancet maintained under sterile conditions until use. Furthermore, the  
18           lancet assembly should be disposable to eliminate the chances of  
19           disease transmission due to the blade being used on more than one  
20           person. In this regard, the lancet should ideally be designed for only  
21           one firing, and have safety features to prevent reuse. Other features

1 which are desirable include safety features to reduce the chance of the  
2 lancet accidentally misfiring and pricking someone.

3 It is therefore an object of the present invention to provide a safe and  
4 reliable lancet assembly.

5

#### 6 BRIEF DESCRIPTION OF THE DRAWINGS

7 Figure 1 is a perspective view of the trigger in Fig. 1 with the side walls  
8 cut away to expose the internal features.

9 Figure 2 is the bottom view of the trigger according to the present  
10 invention.

11 Figure 3A is an exploded perspective view of the lancet assembly  
12 according to the present invention.

13 Figure 3B is an exploded cross-sectional view of the lancet assembly  
14 along line A-A according to the present invention.

15 Figures 4A and B are longitudinal cross-sectional views along line A-A of  
16 the lancet assembly in the after use and firing positions respectively  
17 according to the present invention.

18 Figures 4C and D are longitudinal cross-sectional views along line A-A  
19 of the lancet assembly in the standby position with (Fig.4C) or without  
20 (Fig.4D) the protective cap according to the present invention.

21

1     **SUMMARY OF THE INVENTION**

2     Accordingly, the present invention provides in one aspect a lancet  
3     assembly having a distal end, a proximal end and a longitudinal axis  
4     running therebetween. The trigger is partially inserted into a lancet  
5     holder from the distal end. The lancet holder is provided with a rigid  
6     internal spring holder to receive a spring-loaded lancet structure. The  
7     lancet structure is provided with a body coupled to a spring which  
8     extend from the proximal end of the body. A lancet is attached to the  
9     body with the sharp tip pointing towards the distal end. The trigger  
10    interacts with the lancet holder via a triggering element to maintain the  
11    spring in a compressed state such that the lancet structure is in a  
12    stable standby position which is not easily triggered by accidental  
13    bumps on the assembly. The standby position is automatically  
14    maintained, and an additional arming step is eliminated. In another  
15    aspect, the assembly is provided with a safety feature to prevent  
16    tampering of the lancet assembly. In yet another aspect, the spring is  
17    secured to the end wall of lancet holder such that dislocation caused  
18    by the sudden expansion force of the firing process is prevented.  
19    Furthermore, the spring is chosen to over-extend upon firing, such that  
20    the sharp tip of the lancet can jab a patient's skin held outside the  
21    lancet holder upon firing, but the sharp tip is withdrawn safely back into  
22    the lancet assembly when the spring is recoiled into the resting  
23    position.

1        In another aspect, a method is provided for finger pricking using a  
2        lancet assembly with a distal end and a proximal end. This lancet  
3        assembly contains a lancet with a sharp tip that fires outwards from  
4        the distal end when the assembly is compressed inwards from the  
5        same distal end. The method involves placing the distal end of the  
6        lancet assembly onto a finger to be pricked, and pressing the  
7        assembly into the finger from the proximal end. This compresses the  
8        assembly and causes firing of the lancet whereby the finger is pricked.

9        In the preferred embodiment, the lancet holder is provided with an  
10       open distal end and a closed proximal end defined by an end wall.  
11       Side walls extend from the end walls to form a box-like exterior casing.  
12       A mating element, preferably disposed on the interior surface of the  
13       side walls, is provided to interact with the trigger. The lancet holder  
14       also contains an elongated spring holder having an open first end and  
15       a second end attached to and extending from the end wall of the lancet  
16       holder. The supporting structures between the first end and the  
17       second end define an interior space wherein the lancet structure is  
18       received. A receiving element is provided on the spring holder for  
19       mating with a guiding element on the lancet structure such that the  
20       lancet can move along the longitudinal axis. A securing element is  
21       provided near the proximal end of the lancet holder for securing the  
22       proximal end of the spring from dislocation during firing.

1       The trigger contains an end wall for closing the open distal end of  
2       the lancet holder. This trigger end wall contains an aperture  
3       wherethrough the sharp tip of the lancet fires when triggered. A  
4       stabilizing element, extending from the trigger end wall, is inserted  
5       between the side walls of the lancet holder and the supporting  
6       structures of the spring holder, allowing sliding movement of the  
7       trigger relative to the lancet holder along the longitudinal axis. This  
8       sliding movement is limited by a safety catch on the trigger which is  
9       designed to engage the mating element of the lancet holder such that  
10      the trigger is maintained between a standby position and a firing  
11      position. A triggering element is also provided in the trigger for  
12      engagement with the guiding element of the lancet structure. When the  
13      trigger and the triggering element are in the standby position, the  
14      guiding element is forced towards the proximal end of the lancet  
15      holder, such that the spring is maintained in the standby position of a  
16      compressed high potential energy state. When a compression force is  
17      applied to the trigger end wall in the direction of the proximal end, the  
18      triggering element may be moved into a firing position in which it is  
19      disengaged from the guiding element. Once the guiding element is no  
20      longer held in the standby position, the potential energy stored in the  
21      compressed spring is released and the spring extends, forcing the  
22      sharp tip of the lancet structure to fire through the aperture of the  
23      trigger end wall.

**CLAIMS :**

- 1 1. A lancet assembly comprising :
  - 2 a lancet structure comprising
    - 3 a body having a proximal end and a distal end and a guiding
    - 4 element;
    - 5 a lancet with a sharp tip, attached to said body, such that the sharp
    - 6 tip extend from the distal end of said body; and
    - 7 a spring coupled to and extending from the proximal end of said
    - 8 body, said spring having a linear axis of compression;
  - 9 a lancet holder comprising
    - 10 an open distal end;
    - 11 an end wall at the proximal end;
    - 12 side walls with mating element, extending from said end wall,
    - 13 a spring holder having
      - 14 an open first end,
      - 15 a second end attached to said end wall; and
    - 16 supporting structures therebetween defining an interior space,
    - 17 said lancet structure received within said interior space with
    - 18 said sharp tip proximate said open first end, said supporting
    - 19 structure further provided with a receiving element for

1     **DESCRIPTION OF THE INVENTION**

2     The lancet assembly according to the present invention has a  
3     longitudinal axis defined by the axis of compression of the spring. The  
4     triggler (or triggering device) and the lancet holder interact by keeping  
5     the spring of the lancet structure in a standby compressed state. Upon  
6     compression of the assembly along the longitudinal axis by the user  
7     pressing the end wall of the triggler onto the skin of a patient, the  
8     lancet will be fired to pierce the skin.

9     The following detailed description describes the preferred  
10    embodiment for implementing the underlying principles of the present  
11    invention. One skilled in the art should understand, however, that the  
12    following description is meant to be illustrative of the present invention,  
13    and should not be construed as limiting the principles discussed  
14    herein. In the following discussion, and in the claims the terms  
15    "including", "having" and "comprising" are used in an open-ended  
16    fashion, and thus should be interpreted to mean "including but not  
17    limited to .....".

18    Fig. 1 shows an embodiment of the lancet holder 26 with the side  
19    walls cut away to reveal the spring holder 36. A spring 45a is shown in  
20    dotted line. In this embodiment, the spring holder 36 is generally  
21    shaped into a cylinder with an open first end 102, and a second end  
22    104 attached to the end wall 30 of the lancet holder. Two slits 106,  
23    running from the open first end towards the proximal end are provided

1 on the side wall of the spring holder. In this embodiment, a wider slot  
2 **108** is further cut into the side wall of the spring holder. To strengthen  
3 the side walls of the spring holder, two ridges **112** are provided to  
4 connect the side walls of the spring holder and the lancet holder. This  
5 improves the rigidity of the spring holder, and hence the reliability and  
6 accuracy of the firing procedure. An additional pair of lugs **114** is  
7 provided at the proximal end of the spring holder juxtaposing the two  
8 sides of slot **108**. These lugs can interact with a u-shaped extension  
9 **47** in the spring. The lancet holder is preferably made from a rigid  
10 plastic material with good mechanical strength such as polycarbonate  
11 material in order to withstand the high energy firing process of the  
12 metal spring.

13 Figure 2 shows detailed features of the trigger **50**. In this  
14 embodiment, the trigger is of a rectangular shape having an end wall  
15 **52** with aperture **54**. Side walls **58** extending from the four corners of  
16 end wall **52** to form a stabilizing element. The triggering element, in the  
17 form of actuating ribs **56** extends from two opposing sides of end wall  
18 **52**. A small protrusion, in the form of wedge **60**, is provided at the end  
19 of each actuating rib **56**. Wedge **60** protrudes into the interior of the  
20 trigger. Two L-shaped clips **62** further extend from opposing sides of  
21 end wall **52**. The trigger is preferably made from a slightly flexible  
22 plastic, such as Acrylonitrile Butadiene Styrene (ABS) material to allow  
23 the actuating ribs to bend with the right resistance.

1        Figures 3A, 3B and 4A-D show how the lancet assembly, having a  
2        longitudinal axis 38, a distal end 22 and a proximal end 23, is  
3        assembled to provide the desired features. The lancet structure  
4        includes a lancet body 40, a lancet 44 with a sharp tip 46, and a spring  
5        45 with a linear axis of compression. In this embodiment, spring 45 is  
6        a helical metal coil, and has a U-shaped extension 47 at the proximal  
7        end. Lancet body 40 is provided with channel 42 for receiving and  
8        securing the lancet such that the sharp tip 46 of the lancet is at the  
9        distal end. Guiding pins 48 are provided on opposing sides of body 40.  
10       Securing pins 49 extend from the proximal end of body 40 for securing  
11       spring 45 onto the body.

12       The assembled lancet structure is received within spring holder 36  
13       with spring 45 pressed onto end wall 30 of lancet holder 26. Guiding  
14       pins 42 are slotted into slits 106 such that lateral movement and  
15       rotational movement around the longitudinal axis is prevented. The  
16       spring 45 is fitted onto the lancet body 40 such that the U-shaped  
17       extension 47 extends through slot 108 and wraps around either one of  
18       lug 114. This arrangement prevents the spring from being easily  
19       dislocated from the spring holder during the firing process.

20       The side walls 58 of trigger 50 are slidably inserted into the space  
21       between the spring holder 36 and the side walls 32 of the lancet  
22       holder such that the small wedges 60 of actuating ribs 56 slide  
23       through slits 106 and press the guiding pins towards the proximal end

1 of the lancet holder. The L-shaped clip 62 on the trigger is adapted to  
2 engage the elongated recess 34 on the lancet holder to limit the  
3 longitudinal movement of the trigger relative to the lancet holder.

4 During assembly, the trigger is pressed down toward the lancet  
5 holder in the direction shown by arrow 120, and in the process, the  
6 guiding pins, are forced down concomitantly by the small wedges on  
7 the actuating ribs. This compression force compresses the spring. As  
8 the trigger is pressed lower, the resistance of the spring to further  
9 compression becomes greater. When the resistance of the spring  
10 exceeds the mechanical strength of the actuating ribs to push on the  
11 guiding pins, the actuating ribs are bent outwards relative to the  
12 longitudinal axis of the lancet holder, releasing the compression of the  
13 lancet structure and resulting in firing of the lancet.

14 In the preferred embodiment, a cap 66 is provided to interact with the  
15 side walls 32 of the lancet holder to maintain sterility and to protect  
16 users in cases of accidental firing. The cap is preferably an air-seal or  
17 sterile cap.

18 In the standby position, the resistance of the spring to compression  
19 forces clip 62 towards the distal end of recess 34. In the most  
20 preferred embodiment, the length of actuating ribs 56 is designed to  
21 allow the end wall of the trigger to extend a short distance 41 from the  
22 side walls 32 of the lancet holder when the assembly is in the standby  
23 position, for example, 12 mm from the distal end. This short distance

1 means that the trigger is well protected from firing due to accidental  
2 bumping. Furthermore, due to the lack of lateral movement, the  
3 direction of the external pressure has to be very close to the  
4 longitudinal axis of the assembly in order for the trigger to be  
5 compressed sufficiently for firing to occur. The mechanical strength of  
6 the actuating rib may be designed such that deformation (i.e. firing)  
7 only occurs when sufficient pressure is provided on the trigger end  
8 wall. In addition, the spring may be chosen such that triggering only  
9 occurs when the trigger is flush against the edge of the proximal end  
10 of the lancet holder, or even pushed slightly inside. All these  
11 parameters may be varied to reduce the chance of accidental firing  
12 without undue experimentation. When the user wants to prick the finger  
13 of the patient, he presses the end wall 52 of the trigger against the  
14 skin of the finger. This compression force pushes clip 62 towards the  
15 proximal end of the recess and the trigger towards the proximal end of  
16 the lancet holder, increasing the compression of the spring. This  
17 causes the spring to generate an opposing extension force, which  
18 pushes against wedges 60 of the actuating ribs 56. Ribs 56 are  
19 designed to bend outwards into the firing position with this additional  
20 pressure, in which wedges 60 disengages from guiding pin 48,  
21 causing the spring to fire into a fully extended position and the lancet to  
22 jab the skin of the patient. It is clear that from the above description, the  
23 triggering mechanism is from the interaction with the patient's skin. As

1 a result, if the patient pulls back his hand just when the user is about  
2 to press down the trigger, triggering would not occur.

3 The slot 108 and lug 114 at the proximal end of spring holder acts as  
4 the securing element of the spring such that after firing, the distal end  
5 of the spring recoils towards the proximal end. In this way, the sharp tip  
6 of the lancet is retracted completely back into the lancet holder after  
7 firing. This is a highly desirable safety feature.

8 While the present invention has been described particularly with  
9 references to the aforementioned figures, it should be understood that  
10 the figures are for illustration only and should not be taken as limitation  
11 on the invention. It is contemplated that many changes and  
12 modifications may be made by one of ordinary skill in the art without  
13 departing from the function, spirit and the scope of the invention  
14 described, examples of which are described below.

15 The stabilizing element in the present invention, described as side  
16 walls 58 at the four corners of the trigger 50 in above embodiment,  
17 serves not only as a structure to allow interaction between the trigger  
18 and the lancet holder, but also a structure to prevent lateral  
19 movements therebetween. As a result, only firm compressional  
20 pressure almost directly along the longitudinal axis is required for  
21 firing to occur, and accidentally knocking the trigger in any other  
22 direction is not likely to cause firing. Besides having side walls on all  
23 four corners, other embodiments may be possible, such as rigid

1 structures symmetrically extending from the end walls of the trigger.

2 The tight association between the trigger and the lancet holder also

3 means that the lancet structure is completely protected and enclosed,

4 and it is extremely difficult to dismantle the assembly without breaking

5 some parts.

6 The securing element may be other structures in the molded plastic

7 spring holder that allows interaction of the proximal end of the spring

8 with the proximal end of the lancet holder. This securing element

9 allows a metallic helical spring with superior springback properties to

10 be used instead of plastic springs that may be fabricated as an

11 integral part of the spring holder.

12 Besides a recess on the interior side wall of the lancet holder, other

13 structures, such as an elongated aperture or a bracket in the side wall

14 may also serve as the mating element. A structure which is only

15 accessible from the interior is, however, preferred as it prevents

16 external tampering.

20 engagement with said guiding elements to allow movement of  
21 said body along the axis of compression;

22 a trigger, inserted into said holder, said trigger comprising

23 a trigger end wall for closing said distal end of said holder and  
24 having an aperture wherethrough said sharp distal tip of said  
25 lancet fires when triggered;

26 a stabilizing element, extending from said trigger end wall and  
27 inserted between said side walls and said supporting structures  
28 for sliding movement along the axis of compression, said  
29 stabilizing element further limiting movement of said trigger  
30 lateral to said axis of compression;

31 a safety catch, engaging said mating element of said holder, for  
32 maintaining said trigger between the standby and firing  
33 positions; and

34 a triggering element for engagement with said guiding element, said  
35 triggering element in the standby position maintaining said spring  
36 in a high potential energy compressed state by forcing said  
37 guiding element towards the proximal end of said holder, said  
38 triggering element further movable to said firing position when  
39 external compression pressure is applied to said trigger end  
40 wall, said triggering element in said firing position being  
41 disengaged from said guiding element such that said spring is

42 released from said compressed state and the sharp distal end of  
43 said lancet structure is fired through said aperture of said trigger  
44 end wall.

1 2. A lancet assembly according to claim 1 wherein said lancet holder  
2 further comprises a securing element, connected to said proximal end  
3 of said lancet holder, for securing the proximal end of said spring to  
4 the proximal end of said lancet holder.

1 3. A lancet assembly according to claim 2 wherein said securing element  
2 is at least one lug provided on the external surface of said spring  
3 holder proximate said end wall; said lug engaging an extension of said  
4 spring on the proximal end for coupling to said lug.

1 4. A lancet assembly according to claim 3 wherein said spring holder  
2 further comprises a slot along the length of said supporting structures  
3 wherethrough said extension of said spring can access the lug for  
4 coupling.

1 5. A lancet assembly according to claim 1 wherein said guiding element  
2 comprises a plurality of guiding pins extending laterally from at least  
3 two sides of said body.

1 6. A lancet assembly according to claim 5 wherein said receiving  
2 element comprises a plurality of longitudinal slits within said  
3 supporting wall wherethrough each of said guiding pins extend.

1 7. A lancet assembly according to claim 1 wherein said safety catch  
2 comprises L-shaped clips extending from two opposing sides of said  
3 trigger end wall, and said mating element comprises recesses in the  
4 interior of said side wall of said lancet.

1 8. A lancet assembly according to claim 1 wherein said triggering  
2 element comprises a pair of actuating ribs with wedged ends  
3 extending from two opposing sides of said trigger end wall; and said  
4 guiding element comprises a pair of guiding pins extending laterally  
5 from two opposing sides of said body, said trigger inserted into said  
6 lancet holder such that said wedged ends engage said guiding pins,  
7 said actuating rib in the armed position maintaining said spring in a  
8 high potential energy compressed state by forcing said guiding pin  
9 towards the proximal end of said lancet holder, said actuating rib  
10 further bendable to said firing position when external compression  
11 pressure is applied to said trigger end wall.

1 9. A lancet assembly according to claim 1 wherein said lancet holder  
2 further comprising ridges attached to said spring holder and said  
3 lancet holder to strengthen said supporting structure.

1 10. A lancet assembly according to claim 1 further comprising a cap for  
2 covering up said aperture.

1 11. A lancet assembly according to claim 1 further comprising an air-seal  
2 cap for covering up said aperture and maintaining sterility.

1 12.A lancet assembly comprising :

2 a lancet structure comprising

3 a body having a proximal end, a distal end and a longitudinal axis;

4 a lancet having a sharp tip, said lancet attached to said body such

5 that the lancet extend from the distal end of said body;

6 a plurality of guiding pins extending laterally on opposing sides said

7 body; and

8 a helical metallic spring coupled to said body and extending from the

9 proximal end along said longitudinal axis;

10 a lancet holder comprising

11 an open distal end;

12 an end wall at the proximal end;

13 side walls extending from said end wall with two opposing side walls

14 having a recess on the interior surface;

15 a spring holder having

16 an open first end,

17 a second end attached to and extending from said end wall; and

18 supporting wall therebetween defining an interior space, said

19 lancet structure received within said interior space with said

20 sharp tip proximate said open first end, the dimensions of

21           said space limiting the lateral movement of said lancet  
22           structure, said supporting wall provided with slits  
23           wherethrough said guiding pins extend to allow longitudinal  
24           movement of said lancet structure;

25 a trigger, inserted into said holder, said trigger comprising

26       a trigger end wall for closing said distal end of said holder; said  
27       trigger end wall substantially parallel to said axis of compression  
28       and having an aperture wherethrough said sharp distal tip of said  
29       lancet fires when triggered;

30       trigger side walls extending from said trigger end wall and inserted  
31       between said side walls of said lancet holder and said  
32       supporting wall for sliding movement along the longitudinal axis  
33       while limiting lateral movement of said trigger;

34       a safety catch, extending from said trigger end wall and engaging  
35       said recess of said holder, for maintain said trigger inside said  
36       lancet holder between an standby position and a firing position;  
37       and

38       a pair of actuating ribs with wedged ends, extending from said  
39       trigger end wall, for engagement with said guiding pins, said  
40       actuating rib in the standby position maintaining said spring in a  
41       high potential energy compressed state by forcing said guiding  
42       element towards the proximal end of said lancet holder, said

43        actuating rib further bendable to said firing position when external  
44        compression pressure is applied to said trigger end wall, said  
45        wedge in said firing position being disengaged from said guiding  
46        pin such that said spring is released from said compressed state  
47        and the sharp distal end of said lancet structure is fired through  
48        said aperture of said trigger end wall.

1        13. A method of pricking finger comprising :

2        providing a finger-pricking apparatus with a distal end and a  
3        proximal end defining a longitudinal axis therebetween, said  
4        apparatus having a lancet that fires outwards from said distal  
5        end along said longitudinal axis when said apparatus is  
6        compressed inwards from said distal end along said  
7        longitudinal axis;

8        placing said distal end of said lancet on a finger to be pricked; and

9        pressing said apparatus onto said finger along said longitudinal  
10        axis from said proximal end to cause firing of said lancet and  
11        pricking of said finger.

4/4

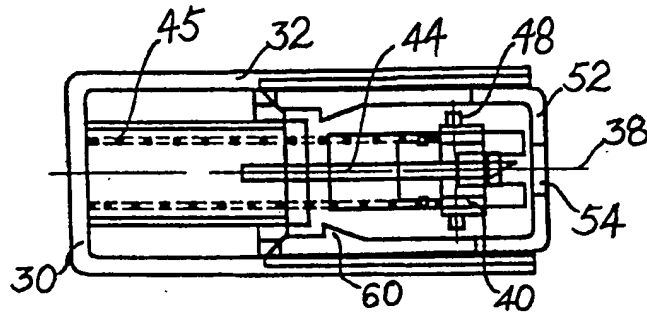


FIG. 4A

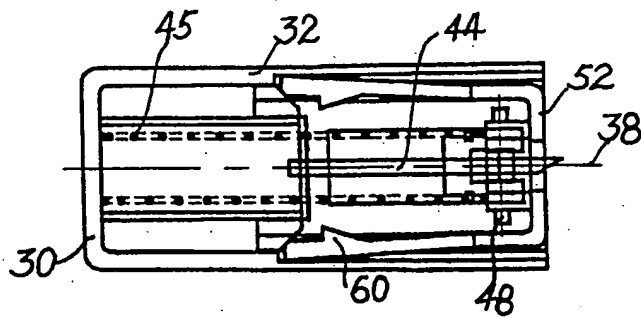


FIG. 4B

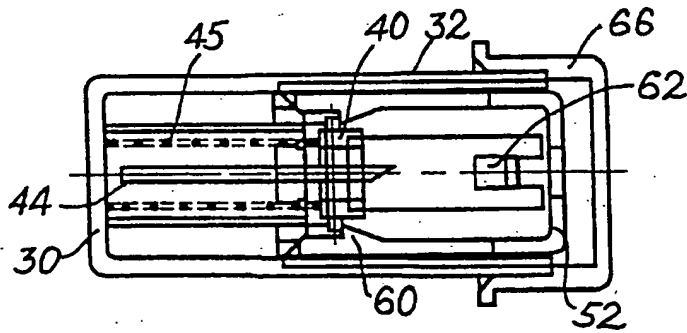


FIG. 4C

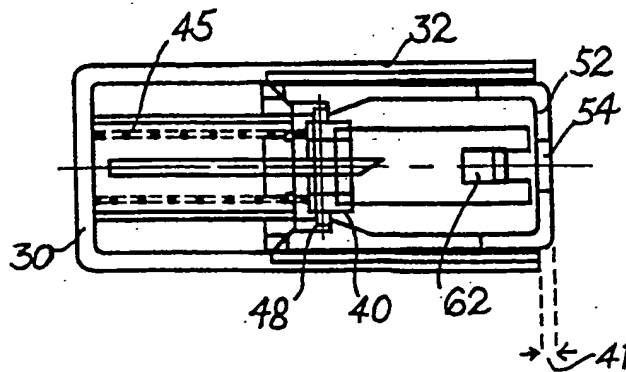


FIG. 4D

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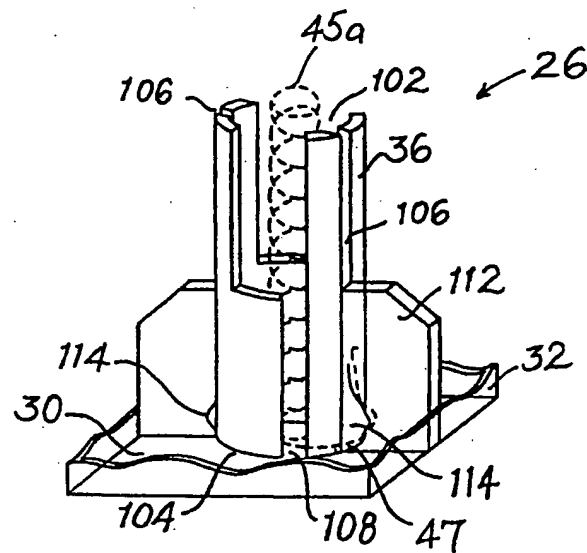


FIG. 1

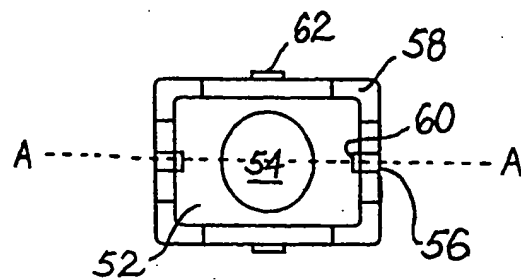


FIG. 2

